IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE DIGITEK®
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANTS' BRIEF OPPOSING CLASS CERTIFICATION

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INTRODUCTION AND SUMMARY OF DEFENDANTS' OPPOSITION

Plaintiffs seek to certify a class of everyone in the United States who may have suffered economic loss (purchase price, replacement cost, or other out-of-pocket expenses) from the recall of a prescription drug, asserting theories such as breach of warranty and consumer fraud. They do not cite a single case in which any court has agreed to certify such a class. Nor do they cite, let alone distinguish, any of the cases in which similar certification requests have been rejected. *See, e.g.*, *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 203-04 (D. Minn. 2003) (collecting cases). Different courts have cited different obstacles to certification, but they agree that certification is not appropriate. Plaintiffs have not met their burden to show the result here should be different.

For example, courts recognize that individual issues arise from the need to determine whether class members received full benefit, no benefit, or something in between, from a recalled product. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2003). They hold that problems of proof may create enormous difficulties in managing a proposed action. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 214 F.R.D. 614, 616-21 (W.D. Wash. 2003). Products liability actions, and those involving prescription drugs in particular, differ from "mass tort" cases because of individual issues as to proximate cause and affirmative defenses. *In re Baycol*, 218 F.R.D. at 203-04.

Plaintiffs must first clear the hurdle of Rule 23(a), which they cannot do. The named plaintiffs' testimony shows that their claims are not typical of those of absent class members; they cannot be, because the named plaintiffs differ even from each other. Some of the named plaintiffs *concede* they suffered no economic loss, and whether any class member did would require individual inquiry. Plaintiffs' class representatives here demonstrate how individual

issues predominate on levels of proof, harm, and causation. Further, Plaintiffs' abandonment of personal-injury claims renders them inadequate representatives.

Courts also agree that choice-of-law issues inherent in a proposed nationwide class generally make certification improper, and that it is no solution for plaintiffs to limit their claims to economic loss. *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016-17 (7th Cir. 2002) (Easterbrook, J.). With regard to choice of law, a movant is required to analyze that problem in detail and provide a trial plan showing how a court could manage an action in which many states' laws must be applied. *Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 370 (4th Cir. 2004). Plaintiffs have not done this, instead simply asserting that the law of New Jersey can somehow govern the claims of every class member nationwide, despite the fact that claimants and these cases come from many different states. But Plaintiffs have the burden of showing that common questions predominate, and parties who propose a multistate class "*cannot meet this burden* when the various laws have not been identified and compared." *Id*. (emphasis added). Plaintiffs did not identify or compare other states' laws, or show how this Court could manage a trial plan with the different laws. That alone defeats Plaintiffs' motion here. As the Seventh Circuit held in *Bridgestone*, the "conclusion that one state's law would apply to claims by consumers throughout the country . . . [would be] a novelty . . . ." 288 F.3d at 1016. The same is true today.

Plaintiffs say little to address any of the above problems or authority.[1] They rely primarily on a New Jersey case that, as discussed below, did not involve pharmaceuticals and that is currently being reconsidered because of a contrary Third Circuit ruling. Their choice-of-law analysis is incorrect, and the proper analysis shows that certification is not warranted. That is a primary reason why common issues do not predominate and Rule 23(b)(3) is not met. For that and the other reasons discussed below, the Court should deny Plaintiffs' motion.

FACTS PERTINENT TO THE LEGAL ISSUES BEFORE THE COURT

- **Digitek®, Its Manufacturers and Distributors**

Digitek®, a tablet of digoxin, is an FDA-approved prescription medicine used to treat heart conditions including atrial fibrillation.[2] Digoxin has a narrow therapeutic/toxic ratio, which means there can be a fine line between sub-therapeutic, therapeutic, and toxic doses. Individual response to digoxin is highly variable and daily oral adult doses typically vary from 0.125 mg to 0.5 mg.[3] For that reason, and because digoxin may interact with other drugs such as diuretics, doctors and other clinicians who prescribe digoxin must monitor patients for therapeutic

[1] The cases cited are by no means the only ones in accord. *See also, e.g.*, *Solo v. Bausch & Lomb Inc*., Nos. 2:06-MN-77777 and 2:06-CV-02716, 2009 WL 4287706, at *2, 7 (D.S.C. Sept. 25, 2009) (denying certification of proposed multi-state class seeking recovery for unused contact lens solution); *Kleinman v. Merck & Co., Inc.*, Nos. ATL-L-4954-04, ATL-L-24-05, 2009 WL 2481925 (N.J. Super. L. Aug. 13, 2009) (reaffirming denial of certification of proposed nationwide, economic-only class of Vioxx users); *In re ConAgra Peanut Butter Prods. Liab. Litig.*, 251 F.R.D. 689, 699 (N.D. Ga. 2008) (denying certification in action filed after peanut-butter recall); *Williams v. The Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003) (dismissing proposed economic-only class in case involving OxyContin); *Feinstein v. Firestone Tire & Rubber Co.*, 535 F. Supp. 595,603 (S.D.N.Y. 1982) (denying certification of proposed class following tire recall); *accord Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320-21 (5th Cir. 2002) (dismissing proposed economic-only class in drug-recall case because plaintiffs did not allege drug was defective as to them, and so lacked standing).

[2] Affidavit of Chris Young (Exh. A) at ¶ 2.

[3] Affidavit of Walter A. Kernan, M.D. (Exh. B) at ¶ 5.3.2. Digoxin has a "half-life" (time until the serum concentration falls by 50%) of 1 to 2 days in a person with normal kidney function. *Id*. ¶ 5.2.2. Renal problems may therefore cause toxicity if digoxin dosage is not carefully monitored. *Id*. at ¶ 5.3.3.

response and toxicity.[4] Digoxin therapy is associated with important dose-related toxicities primarily in the gastrointestinal and cardiac systems.[5] Gastrointestinal toxicities may include loss of appetite, diarrhea, nausea and vomiting, but these are non-specific symptoms that may have many other causes.[6] Likewise, digoxin toxicity may result in a variety of cardiac rhythm disturbances, but again, these are non-specific and may occur in the absence of digoxin therapy.[7] Indeed, most symptoms of digoxin toxicity are non-specific and may have many other causes.[8]

Any estimation of the likelihood that a patient has experienced digoxin toxicity requires careful examination of highly individualized clinical information.[9] To estimate the likelihood that digoxin has caused a specific symptom or sign requires a careful review of the details of a patient's symptoms, the symptom course, concurrent drug therapy, a physical examination, diagnostic test results, serum drug concentrations, and subsequent clinical course.[10]

Likewise, the nature and magnitude of digoxin's benefits varies from person to person.[11] That is because digoxin is used to treat different disease conditions among different individuals with differing medical histories.[12] To assess the potential benefit to any individual, a clinician would need to consider the specific circumstances and medical history of that individual.[13]

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[4] *Id*. at ¶¶ 5.3.4, 5.3.5.

[5] *Id*. at ¶ 5.4.1.

[6] *Id*. at ¶ 5.4.2.1

[7] *Id*. at ¶ 5.4.3.1.

[8] *Id*. at ¶ 5.4.4.1.

[9] *Id*. at ¶ 6.3.

[10] *Id*. at ¶ 6.3.1.

[11] *Id*. at ¶ 6.4.

[12] *Id*. at ¶ 6.4.1.

[13] *Id*.

Digitek® was produced by Amide Pharmaceuticals, Inc., until its parent company was acquired by Actavis Group hf in 2005; after that, Actavis Totowa LLC manufactured Digitek® but never distributed it directly to the marketplace.[14] Actavis sold Digitek® to Mylan Pharmaceuticals, Inc.[15] These companies, and the other defendant companies, reside in several different states. The Actavis entities are Delaware business entities with principal places of business in New Jersey.[16] UDL is an Illinois corporation with its principal place of business in Illinois.[17] Mylan, Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business in West Virginia. Finally, Mylan Bertek Pharmaceuticals, Inc. is a seller/distributor that is incorporated in Texas, but has no offices or physical facilities.[18]

- **The Voluntary 2008 Digitek® Recall.**

On April 25, 2008, Actavis initiated a nationwide voluntary Class I recall of Digitek® due to the possibility that tablets of about twice the specified thickness (which therefore may theoretically have had up to twice the expected level of active ingredient) *may* have been commercially released.[19] The recall was initiated after a total of 20 nonconforming tablets were observed in one lot of 4.8 million tablets manufactured in November 2007. Ultimately, the lot was released for distribution on January 28, 2008, following two comprehensive inspections that did not reveal any additional nonconforming tablets.[20] However, following discussions with

[14] Young Aff., ¶ 3. Actavis Totowa is a subsidiary of Actavis, Inc., which is owned by Actavis Group hf. In this brief, the term "Actavis" refers to Actavis Totowa.

[15] Young Aff., ¶ 3.

[16] *See id.* at ¶ 6.

[17] Affidavit of Liana Radtke (UDL's Senior Regulatory and Compliance Director) (Exh. C) at ¶ 2.

[18] Affidavit of Cassandra Bird (Mylan's Senior Director of Quality Assurance) (Exh. D) at ¶ 2.

[19] Young Aff. at ¶ 4.

[20] *Id*. at ¶¶ 4, 5.

FDA, and out of an abundance of caution, Actavis initiated a recall. To date, not a single double-thick tablet has been identified as having reached the market.[21]

When informed of the recall, Mylan and UDL retained an FDA-approved outside recall vendor, Stericycle, Inc., to manage the recall.[22] Under the recall program, a notification packet was sent to wholesalers, pharmacies, hospitals, clinics, and long-term care facilities, as well as some direct accounts, instructing them to (among other things) contact their customers at once.[23] Consumers who responded then received a return kit that allowed them to send in any unused Digitek® and valid pharmacy receipts and receive a refund, while those without valid receipts could still obtain refunds on a per-tablet basis.[24] As the recall/refund program progressed, UDL and Mylan performed Level A (100%) effectiveness checks.[25] The participation and return data reflect a highly successful program.[26] Stericycle continues to process returns to date.[27]

Last year, FDA cited the Digitek® recall as an example of aggressive action taken in response to an event that posed little risk to begin with, explaining that in its best judgment, "given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."[28]

- **Class Action Complaints**

What began as extensive class action litigation has since dwindled to a handful of named class representatives asserting only claims for economic loss; only six complaints remain,

[21] *Id.*

[22] Bird Aff. at ¶ 5; Radtke Aff. at ¶ 5.

[23] Bird Aff. at ¶¶ 6-7; Radtke Aff. at ¶¶ 6-7.

[24] Bird Aff. at ¶ 13; Radtke Aff. at ¶ 13.

[25] Bird Aff. at ¶ 8; Radtke Aff. at ¶ 8.

[26] Bird Aff. at ¶¶ 10-12, 15; Radtke Aff. at ¶¶ 10-12, 15.

[27] Bird Aff. at ¶ 14; Radtke Aff. at ¶ 14.

[28] U.S. Food and Drug Admin., Fact and Myths about Generic Drugs (July 8, 2009) (Exh. E).

brought by eight class representatives. When originally filed, these complaints sought personal injury and medical monitoring in addition to economic damages, and certain ones (*e.g.*, Chambers and York) only requested statewide certifications. As now evolved, however, Plaintiffs uniformly seek nationwide certification and have disavowed all personal injury/medical monitoring class allegations, leaving claims for "economic loss" only, although some Plaintiffs still need to amend their pleadings accordingly.[29]

- **The Named Plaintiffs' Testimony**

The deposition testimony of the eight remaining named plaintiffs and two now-discarded plaintiffs (still putative class members) demonstrates the highly individual nature of the claims. It further reveals a sharp contrast between plaintiffs' counsel's "economic loss" only theory and how their clients view their own claims.

Willie Mae Wilburn

Plaintiffs label Illinois resident Willie Mae Wilburn as the "quintessential Digitek® plaintiff." (Doc. 283-1, at 23.) By calling only one representative "quintessential," Plaintiffs themselves highlight the lack of cohesion even among the eight class representatives, whose claims are all required to be typical of each others' claims and of the class claims.

Wilburn took Digitek® daily from 2005 to April 2008 for heart palpitations, and was diagnosed with atrial fibrillation in February or March 2008.[30] She testified that during the same two months she experienced weakness, dizziness, and palpitations and that now, as a result of taking Digitek®, she has a bad memory and is "tired."[31] She has never told any doctor that she

[29] *See, e.g.,* York Complaint, Case No. 2:09-cv-00544 (Exh. F) (asserting wrongful death and personal injury claims).

[30] Dep. of W.M. Wilburn, taken 8/6/09 (Exh. G), at 51:16-22; Wilburn PFS (Exh. H) at 5, 11.

[31] Wilburn Dep. at 22:2, 14-24, 83:17-19, 86:10-89:19.

thinks Digitek® harmed her in any way, and she has never talked to any doctor or healthcare professional about her memory loss problems.[32] In fact, no doctor ever associated Wilburn's weakness, dizziness, or palpitations in 2008 with her Digitek® use, and she was never diagnosed with digoxin toxicity in that timeframe.[33]

Yet Wilburn seeks economic-loss damages for doctor visits between February and April 2008 due to her weakness and dizziness, as well as a May 2008 emergency room visit for shortness of breath.[34] She also wants reimbursement for two $5.00 co-payments for Digitek® prescriptions.[35] She testified that after the recall, she did not call her doctor; she simply picked up replacement digoxin from the pharmacy the next day.[36] When asked, she could not recall ever having noticed any size difference in her Digitek® tablets; she thought they were "all good."[37]

Although Wilburn makes no personal injury claim, she believes that she represents a *worldwide* group of Digitek® users with a personal injury or pain-and-suffering claim, and she believes that her responsibility as a class representative would be to help herself and other people find out why they heard about Digitek® from the pharmacy rather than the company.[38] Though Wilburn's counsel repeatedly reminded her that she only represents an economic-loss class, she continued to testify that she was seeking to recover damages for other putative class members' personal injuries.[39] Moreover, Wilburn did not understand that by limiting putative class

[32] *Id*. at 119:23-120:6, 121:23-25.

[33] *Id*. at 26:19-22, 78:9-11, 86:14-16, 89:12-15.

[34] *Id*. at 20:8-21:18, 73:6-14, 92:1-93:19, 128:16-129:1.

[35] *Id*. at 73:6-14.

[36] *Id*. at 15:5-18, 17:15-18.

[37] *Id*. at 3838:13-14.

[38] *Id*. at 95:4-11.

[39] *Id*. at 96:19-21.

members' claims to economic losses, she would be preventing them from filing a personal injury claim in the future, and she did not think such a result would be fair.[40]

Peter J. Konek

Kansas resident Peter Konek allegedly took Digitek® from November 2007 to April 2008.[41] He does not claim that he suffered any physical injuries – his goal is only to see the companies "punished."[42] He did not personally experience any anxiety due to his ingestion of Digitek®, but seeks to recover damages for those who may have.[43]

In terms of economic loss, Konek seeks $2.21 to reimburse him for the 17 tablets he had remaining after the recall, and also seeks $20.00 for co-pays. He seeks the $2.21 reimbursement even though he knew he could have simply received a refund via the Stericycle program.[44] And he seeks co-pay reimbursement even though Digitek® "did its job" for him:

> Q. As far as you're concerned with respect to the Digitek® that you took, did it do its job in helping your heart stay in rhythm?
>
> A. I would say that it did. Unless I took one when they put the wrong one in the package.
>
> Q. Well, do you have any specific recollection of taking –
>
> A. No, I don't.
>
> * * *
>
> Q. Do you believe that you received that benefit from taking Digitek®?
>
> A. Yes.[45]

[40] *Id.* at 98:17-22; 99:6-11.

[41] Konek PFS (Exh. I), at 4.

[42] Dep. of P. Konek, taken 7/27/09 (Exh. J), at 79:12-13; *see id.* at 87:21-24 ("I've told you once and I'm telling you again I don't care. I just want to see this company punished for doing what they did . . . ").

[43] *Id.* at 25:22-26:4.

[44] *Id.* at 77:23-78:25.

[45] *Id.* at 55:11-56:11.

After the recall, Konek did not go to his doctor – he simply called his doctor's office and received a replacement prescription the next day.[46] He does not know if he ever took an out-of-specification Digitek® tablet and has "no idea" whether any such tablets ever made it to market.[47] Konek never noticed any difference in the physical size of his Digitek® tablets, nor has he ever been diagnosed with digoxin toxicity.[48]

Konek agreed that defense counsel would have to talk to each Digitek® user to determine whether each was asserting personal injury or economic claims, as well as what subtype (*e.g.*, a lost-wage claim, which Konek does *not* assert).[49] He admitted (in response to a question by his own counsel) that he did not understand his duties or responsibilities as a class representative.[50]

Judy Whitaker

Judy Whitaker is the daughter of Kentucky resident Anna Fight, who died in May 2007 after a stroke.[51] The decedent apparently took some form of digoxin in February 2007 and in April 2007, although the medical records are unclear as to whether she actually took Digitek® as opposed to some other brand of digoxin.[52] Whitaker testified that her mother felt "weak and tired" from digoxin in February 2007, and that the cardiologist discontinued it at the end of February or March 2007.[53] Whitaker clarified that her mother's cardiologist stopped the digoxin

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[46] *Id*. at 19:6-12.

[47] *Id*. at 24:3-5; *see also id*. at 80:15-17 ("Well, I don't know whether I took one that they took off the shelf. I have no idea. You tell me.").

[48] *Id*. at 56:18-25, 57:1.

[49] *Id*. at 27:15-28:18.

[50] *Id*. at 105:3.

[51] Dep. of J. Whitaker, taken 12/11/09 (Exh. K), at 8:20-23, 10:2-12:14, 33:22-34:18.

[52] Whitaker PFS (Exh. L) at 5.

[53] Whitaker Dep. at 13:22-14:11, 43:21-45:23.

"as a result of anorexia, after Ms. Fight had nausea, weakness and weight loss."[54] When Whitaker asked her mother's cardiologist to discontinue the medication in February 2007, she had no reason to believe that it was not effective in treating the heart condition.[55]

Almost a year after her mother's death, Whitaker learned that Digitek® had been recalled. She now believes that Digitek® caused her mother's weight loss, and ultimately two strokes, the second one fatal.[56] No one has ever told Whitaker that her mother's strokes were caused by Digitek®, but she continues to believe that her mother died solely because she took Digitek® *or* some other brand of digoxin – Whitaker is not sure which.[57] She believes Digitek® and digoxin are the same, and used the terms interchangeably throughout her deposition.[58]

Whitaker asserts a personal injury wrongful death claim in her class complaint, and, as her counsel stated on the record, she intends to pursue this claim here despite the fact that she is not seeking to represent the putative class for their personal injury complaints.[59] Plaintiffs claim that Whitaker has some of her mother's Digitek® "for which she had paid" in 2007 (Doc. 283-1, at 32), but those tablets did not go unused because of the April 2008 recall. In fact, Whitaker admitted that she has not suffered any economic loss, but is comfortable representing a class of people who might have suffered such loss.[60] She believes she is representing all Kentucky

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[54] Exh. L at 4.

[55] Whitaker Dep. at 135:6-13.

[56] Exh. L at 5.

[57] Whitaker Dep. at 51:20-22, 127:13-16.

[58] *Id*. at 94:19-25.

[59] *Id*. at 69:23-70:1. The *York* complaint also includes several named plaintiffs who their counsel claims are *not* proposed class representatives, just individuals who will assert their own personal injury claims in the same case as the proposed class action. (*See, e.g*., Exh. F.)

[60] *Id*. at 76:7-16.

residents who have experienced economic loss as a result of taking Digitek®.[61] She also hopes the government will "step in and be a little bit more aware" of what is being distributed.[62]

Lorena Ard

Kentucky resident Lorena Ard started Digitek® following open-heart surgery in 2006.[63] She claims that, from October or November 2007 until May 2008, Digitek® caused her to experience fatigue, shortness of breath, and an irregular heartbeat.[64] In mid-February 2008, she called her cardiologist regarding her irregular heartbeat, but at a subsequent appointment they did not discuss Digitek® and he did not test her blood for digoxin.[65]

Ard stopped taking Digitek® only after she got a recall notification letter. She admitted getting the letter, yet denied knowing about the refund program.[66] Ard seeks lost wages for 120 hours at $42.00 per hour, a $20.00 co-pay for a doctor visit, and any other uninsured hospital admission costs.[67] She also seeks to recover emotional distress damages on behalf of herself and the class.[68] Although Ard, who is a nurse, claims the Digitek® she took posed health risks, she cared for a patient who was taking Digitek® but did not tell the patient about this lawsuit.[69]

Dale Campbell

Pennsylvania resident Dale Campbell took Digitek® from May 2007 to June 2008. He claims that he experienced dizziness, nausea, and palpitations in May 2008 due to his ingestion

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[61] *Id*. at 60:18-61:24, 76:7-16.

[62] *Id*. at 129:1-131:2.

[63] Ard PFS, attached as Exh. M, at 6; Dep. of L. Ard, taken 12/11/09 (Exh. N), at 10:15-18, 12:10-24.

[64] Ard Dep. at 10:19-11:20.

[65] *Id*. at 29:11-21, 35:8-36:6.

[66] *Id*. at 51:4-14, 97:5-8.

[67] *Id*. at 70:5-72:12.

[68] *Id*. at 98:12-15, 110:1-25.

[69] *Id*. at 7:12-13, 9:17-10:24, 122:6-8.

of Digitek®, but no doctor has ever told Campbell that the symptoms he experienced were related to Digitek® ingestion.[70] Yet Campbell seeks reimbursement for the co-pays he spent to have his Digitek® prescriptions filled.[71]

Campbell has "not a clue" whether any out-of-specification tablets made it to market, or if he ingested any.[72] He noticed nothing unusual about the physical appearance of any of his Digitek® tablets.[73] Like Lorena Ard (but unlike Peter Konek), Campbell denies knowing about the Stericycle refund program although he admitted receiving a recall letter.[74] Campbell has no information regarding the nature of any other putative class member's claims.[75] He concedes that he does not understand the obligations of a class representative, nor does he know how or why he was selected as one.[76]

Alan Chambers

New Jersey resident Alan Chambers took Digitek® from January 23, 2008 to April 30, 2008 to regulate his heart rhythm.[77] He stopped taking Digitek® on his own in March 2008, but later restarted after consulting his cardiologist.[78] He claims that as a result of taking Digitek®, he experienced heart "contractions," though his physician attributed that symptom to an implanted device, not Digitek®.[79] Campbell admitted that while on another brand of digoxin in September

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[70] Dep. of D. Campbell, taken 7/31/09 (Exh. O), at 80:2-8, 87:8-88:15; 102:2-20.

[71] *Id*. at 24:15-18, 107:3-16.

[72] *Id*. at 101:21-102:8.

[73] *Id*. at 86:5-8.

[74] *Id*. at 22:14-23:16.

[75] *Id*. at 26:16-27:2, 110:19-111:8.

[76] *Id*. at 27:12-15, 28:7-11, 75:13-15.

[77] Chambers PFS (Exh. P), at 5.

[78] Dep. of A. Chambers, taken 9/22/09 (Exh. Q), at 89:19-24, 91:1-10.

[79] *Id*. at 15:4-12.

2008, he experienced the same type of contractions he claims to have experienced in March 2008 while on Digitek®.[80]

Chambers seeks $15 in co-pays as well as economic-loss damages for one doctor's visit, although he admitted that this was a regularly scheduled visit that would have occurred whether he had taken Digitek® or not.[81] When Chambers learned of the recall, he neither called his cardiologist nor set up an appointment.[82] He had taken all of his remaining Digitek®, and simply decided on his own not to take anything between the time of the recall and his next scheduled visit in June.[83] Chambers has never been told he experienced digoxin toxicity, and admitted that as a layman he simply does not know whether he received an out-of-specification tablet.[84] In fact, Chambers stated that he received the same benefit from Digitek® that he received from generic digoxin, and does not believe Digitek® was ineffective in treating his condition.[85, 86]

At the time of his deposition, Chambers had not reviewed his complaint; nor did he know that he could have filed an individual action in this MDL.[87] Though he seeks only co-pays and the cost of a regularly scheduled doctor's visit, he intends to seek other types of economic loss damages for other class members, including post-recall medical testing.[88]

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[80] *Id*. at 23:13-17.

[81] *Id*. at 33:15-23, 117:3-14; 31:2-18.

[82] *Id*. at 13:18-14:9.

[83] *Id*. at 14:2-9, 98:9-14.

[84] *Id*. at 101:25-102:12.

[85] *Id*. at 118:22-119:18.

[86] Given the foregoing, Defendants challenge Chambers' standing in a separately-filed motion for summary judgment.

[87] *Id*. at 41:21-23, 104:15-18.

[88] *Id*. at 107:8-109:2.

William Lange

Kentucky resident William Lange took Digitek® from 2003 to April 2008.[89] He lives just a mile from his pharmacy, but nonetheless seeks compensation for the gasoline required for making two trips to obtain replacement digoxin.[90] He also seeks reimbursement for one doctor's visit and a $10.00 co-pay.[91] When Lange received his recall letter, he did not call his doctor, but instead went to the pharmacy.[92] Like Ard and Campbell, although Lange got a recall letter, he claims he was not aware of the refund program.[93] Lange was never diagnosed with digoxin toxicity or elevated digoxin levels.[94] He testified that when he switched from Digitek® to another brand of digoxin, he did not notice anything different in his condition or how he was feeling.[95] In fact, he really does not know whether Digitek® was effective in treating his atrial fibrillation for the many years he was taking it.[96]

- **The Discarded Named Plaintiffs' Testimony**

Bobby Milligan

Shortly after his deposition was taken, Milligan dismissed his case. He remains a putative class member, however, and his testimony underscores the disparity between class members. For example, Milligan took Digitek® from 2004 to April 2008 and testified that, post-recall, he returned 45 unused Digitek® tablets and got replacements at no charge.[97] In other

[89] Lange PFS (Exh. R), at 5.

[90] Dep. of W. Lange, taken 10/6/09 (Exh. S), at 14:20-25, 19:10-24, 42:8-19.

[91] *Id*. at 14:20-25, 21:10-22:18.

[92] *Id*. at 15:3-17.

[93] *Id*. at 23:3-11.

[94] *Id*. at 52:20-23.

[95] *Id*. at 45:1-4.

[96] *Id*. at 45:5-9.

[97] Dep. of B. Milligan, taken 7/16/09 (Exh. T), at 164:12-15.

words, he too sustained no economic loss as a result of the recall. Milligan seeks emotional distress damages, and hopes to recover the cost of a new pair of glasses, based on blurred vision and headaches he experienced in January and February 2008 while on Digitek®.[98] No doctor has ever linked these physical symptoms to Digitek®.[99]

Michael Pasken

Plaintiffs dismissed Florida resident Michael Pasken as a named plaintiff shortly before moving for certification. And for good reason – Pasken's issues are possibly the most individualized of all. Pasken took Digitek® once a day from January to May 2008 for treatment of congestive heart disease.[100] When he heard about the Digitek® recall, he decided to break his Digitek® tablets in half and take half-tablets until his replacement digoxin arrived in the mail.[101]

Pasken testified that between February and April 2008, Digitek® caused an irregular heartbeat and constipation – although of the two, he was more concerned about constipation.[102] This is consistent with part of Pasken's damage claim, because he seeks reimbursement for the money he had to pay to leave a fishing trip and find a pharmacy to buy two enemas (the cost of the enemas, the gasoline required to drive 20 miles, and a $6 toll).[103] He also seeks $462 in canceled trip insurance (he was not feeling well before a planned trip to Alaska). Pasken correctly conceded that the damages sought by other class members would likely differ significantly from his own.[104]

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[98] Milligan Dep. at 39:11-40:23, 45:5-47:6, 65:12-66:7.

[99] *Id*. at 197:17-21.

[100] Pasken PFS (Exh. U) at 5.

[101] Dep. of M. Pasken, taken 7/29/09 (Exh. V), at 46:14-20.

[102] *Id.* at 27:20-31:18 (describing it as the "biggest thing" he suffered as a result).

[103] *Id*. at 36:4-16, 121:18-22.

[104] *Id*. at 133:15-22.

- **Brief Response to Plaintiffs' Statement of the Facts.**

Plaintiffs have presented pages of unsupported and irrelevant facts, discussing matters such as general medical causation, inspection forms, FDA warning letters, and an alleged breach of duties to provide "complete and adequate information about the recalled Digitek®" above and beyond FDA recall protocol. (*See* Doc. 283-1, at 12-22.) Defendants will not address those facts here except to correct two misstatements. First, the recall was not "due to the fact that Defendants manufactured and sold tablets in an Unapproved Excessive Dose . . . ." (Doc. 283-1, at 14.) As noted, there is no evidence that any double-thick tablet ever reached the market. Actavis initiated the recall due to the theoretical possibility that such tablets might have been released. Second, Plaintiffs state that the recall announcement said Digitek® users should "seek medical consultation." (Doc. 283-1, at 12, 22, 34, 51, n.29.) It actually said that "Patients should contact their healthcare professional with questions" about the recall. (*See* Exh. L to Doc. 283-1.)

CLASS CERTIFICATION STANDARDS

Every class action must satisfy the four requirements of Rule 23(a) (commonality, typicality, adequacy, and numerosity) and at least one of the requirements of Rule 23(b). *Gariety*, 368 F.3d at 362. Plaintiffs have the burden of persuading the court that these requirements have been met and that a class should be certified. *Rhodes v. E.I. du Pont de Nemours and Co.*, 253 F.R.D. 365, 372 (S.D. W. Va. 2008) (citing *Thorn v. Jefferson-Pilot Life Ins. Co.*, 445 F.3d 311, 321 (4th Cir. 2006)).

That is a particularly heavy burden in cases, like this one, involving plaintiffs who hope to coast to some financial recovery in the wake of a product recall involving a product that caused them no personal injury. Courts routinely reject certification of proposed "economic-only" class actions involving a product consumed or used without incident. In a case involving

Rezulin, for example, a court refused to certify a proposed nationwide class asserting warranty, unjust enrichment, and NJCFA claims because the recalled drug benefited a large percentage of the proposed class, requiring individual inquiries into that issue. *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. at 68-69.[105] Courts similarly decline to certify proposed classes seeking recovery for leftover, unused product. *See, e.g.*, *In re ConAgra Peanut Butter Prods. Liab. Litig.*, 251 F.R.D. at 699 (denying certification in action filed after peanut-butter recall, because many consumers got full or some value from product and all could still get a full refund).[106]

A plaintiff's burden is even heavier in a proposed multi-state class because the plaintiffs also bear the burden of identifying and comparing the relevant laws of all the states in which representative *and* absent class members reside. *Gariety*, 368 F.3d at 370. "The plaintiffs have the burden of showing that common questions of law predominate, and *they cannot meet this burden when the various laws have not been identified and compared*." *Id.* (emphasis added).

Further, a court cannot accept a plaintiff's factual allegations at face value, but rather should "probe behind the pleadings" to determine whether a class should be certified. *Rhodes*, 253 F.R.D. at 372 (quoting *General Tel. Co. v. Falcon*, 457 U.S. 147, 160 (1982)). A court may not base its certification analysis on whether it thinks a proposed class is likely to win on the

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[105] *See also In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 288 F.3d at 1020 (reversing certification of proposed nationwide class seeking economic damages after tire recall); *Kleinman v. Merck & Co., Inc.*, 2009 WL 2481925 (pinpoint cites unavailable) (reaffirming denial of certification of proposed nationwide, economic-only class of Vioxx users); *In re Baycol Prods. Liab. Litig.*, 218 F.R.D. at 214 (denying certification of proposed class seeking "refund" after drug recall); *Feinstein v. Firestone Tire & Rubber Co.*, 535 F. Supp. at 603 (denying certification of proposed class following tire recall). *Accord Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d at 320-21 (dismissing proposed economic-only class in drug-recall case because plaintiffs did not allege drug was defective as to them, and so lacked standing); *Williams v. The Purdue Pharma Co.*, 297 F. Supp. 2d at 176 (dismissing proposed economic-only class because at least some patients had received the benefit of their bargain from OxyContin because they obtained pain relief without addiction, and "[t]hose who did not, as plaintiffs concede, can be compensated through tort law.").

[106] *See also Solo v. Bausch & Lomb Inc.*, at *2, 7 (denying certification of proposed multi-state class seeking recovery for unused contact lens solution); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 214 F.R.D. at 616 (same where class sought recovery for unused over-the-counter drugs).

merits, but this "does not mean that consideration of facts necessary to a Rule 23 determination is foreclosed merely because they are required to be proved as part of the merits." *Gariety*, 368 F.3d at 366. Indeed, accepting the pleadings for this purpose would be inconsistent with a court's responsibility to take a "close look" at relevant facts, conduct a "rigorous analysis" of the claim, and to make "findings" that Rule 23 requirements have been met. *Id.* at 365 (citing *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615 (1997); *Falcon*, 457 U.S. at 161; and Fed. R. Civ. P. 23(b)(3)); *see also Rhodes*, 253 F.R.D. at 372 (quoting *Falcon*'s "rigorous analysis" standard). A judge must make whatever factual and legal inquiries are necessary under Rule 23, regardless of whether that happens to overlap with merits issues. *Gariety*, 368 F.3d at 366 (quoting *Szabo v. Bridgeport Machs., Inc.,* 249 F.3d 672, 675-76 (7th Cir. 2001)).

LEGAL ARGUMENT

I. Plaintiffs Have Not Met Their Burden to Show All Rule 23(a) Requirements Are Met.

Here, Plaintiffs have made little effort to carry their burden to show that the requirements of Rule 23(a) are met. Defendants do not dispute numerosity, but Plaintiffs have not established commonality, typicality, or adequate representation.

A. Plaintiffs have not met their initial burden to identify common issues and so cannot show such issues predominate.

Whether common issues predominate is discussed in more detail below (*see infra* § II), but Plaintiffs have not even met their initial burden to identify the issues they say are common. In purporting to do so, Plaintiffs do little more than list elements of the causes of action alleged (Doc. 283-1, 40-41), and state without analysis or explanation that this is a "mass tort case[] involving a single product." (*Id.* at 39.) It is hard to see how a scattering of economic-loss cases brought by plaintiffs who do not even claim to have been injured by the recalled product could

qualify as a "mass tort."[107] But even if it did, such cases *may* involve a predominance of common issues, or they may not. It is Plaintiffs' burden to show that these particular cases do.

Further, Plaintiffs must articulate common issues with some specificity, because "at a sufficiently abstract level of generalization, almost any set of claims can be said to display commonality." *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577, 586 (S.D. Ohio 2003) (quoting *Sprague v. General Motors Corp.*, 133 F.3d 388, 397 (6th Cir. 1998) (en banc)). This problem is exemplified by Plaintiffs' approach here, highlighted by the claim that "[w]hether Defendants' conduct . . . *fell below any duty owed* by Defendants" is a common issue. (Doc. 283-1 at 41 (emphasis added).) If such a generic "issue" could qualify as "common," commonality would always exist; every plaintiff alleges a breach of *some* duty under *some* law. Plaintiffs' conclusory, generic discussion of commonality does not meet their burden.

B. Plaintiffs' own testimony shows their claims are not typical of the claims of putative class members.

"The typicality requirement goes to the heart of a representative party's ability to represent a class . . . ." *Deiter v. Microsoft Corp.*, 436 F.3d 461, 466 (4th Cir. 2006). To be sure, typicality does not require that "the plaintiff's claim and the claims of class members be perfectly identical or perfectly aligned," but if the variation strikes at the heart of the causes of action, certification is "readily denied." *Id*. at 467. A named plaintiff's interest in pursuing his or her own case "must simultaneously tend to advance the interests of the absent class members," and he or she has the burden to show this by comparing the claims or defenses involved. *Id*. at 466.

[107] Elsewhere in their brief, Plaintiffs seek to distinguish their cases from "the personal injury / 'mass tort' Digitek claims also before this Court . . . ." *Id*. at 2.

As with commonality, Plaintiffs simply make conclusory statements asserting that typicality is present. (Doc. 283-1, 42-44.) They assume incorrectly that New Jersey law can be applied to every class members' claims, and simply assert that typicality is present because "Plaintiffs and the Class Members are similarly aggrieved by Defendants' conduct," "all assert essentially identical legal claims," and "[n]o conflict exists between the claims of the Plaintiffs and the claims of any other Class member." (Doc. 283-1 at 42.) These are the same sort of conclusory arguments that the *Dieter* court found "unacceptably general." *Deiter*, 436 F.3d at 467 (rejecting generic argument that, for example, "all class members were injured because the price they paid was artificially inflated . . . .").

None of the representatives here could show that proving their cases would necessarily prove a case on behalf of absent class members. *Id.* at 468. Indeed, it is not clear that there is even a representative whose claims are typical of the other *representatives'* claims. For example, representatives (if any) who have economic-loss claims would not prove Judy Whitaker's case even if they prevailed, because she is bringing a wrongful death action. And representatives like Peter Konek or Alan Chambers could not advance anyone's breach-of-warranty or unjust enrichment claims, because they both admitted that Digitek® did just what they had hoped it would do. Similarly, Lange's desire to recover gas money, Milligan's desire to be reimbursed for new glasses, and Pasken's hope for compensation for trip insurance illustrate the wide array of "economic" claims the putative class would expect to assert. There simply is no "typical" claim.

And this is setting aside Plaintiffs' refusal to address the choice-of-law issues that loom over their class action. They assert that New Jersey law applies throughout. If they are wrong (and they are), then the legal claims are dissimilar in ways that they have not even tried to

address. For example, Wilburn hopes to represent a nationwide implied warranty class even though she cannot recover under the Illinois law that governs her own claim. Illinois law requires privity, but Defendants did not sell Digitek® directly to individual consumers. This very problem led the court presiding over Baycol litigation to find an Illinois class representative atypical of the proposed class. *In re Baycol*, 218 F.R.D. at 214. Here, too, this and similar meaningful differences show that typicality is absent.

C. The class representatives will not fairly and adequately represent the interests of the putative class.

"The adequate representation inquiry 'serves to uncover conflicts of interest between named parties and the class they seek to represent.'" *In re Serzone Prods. Liab. Litig.*, 231 F.R.D. 221, 238 (S.D. W. Va. 2005) (citing *Amchem*, 521 U.S. at 625); *see also* Fed. R. Civ. P. 23(a)(4). Courts must "carefully examine" whether the representatives will "fairly and adequately protect the interests of the class." *Walker v. Liggett Group, Inc.*, 175 F.R.D. 226, 231 (S.D. W. Va. 1997). To adequately represent a class – a duty that requires "undivided loyalt[y] to absent class members" – class representatives "must be part of the class and 'possess the same interest and suffer the same injury' as the class members." *Broussard v. Meineke Discount Muffler Shops, Inc.*, 155 F.3d 331, 338 (4th Cir. 1998) (citing *East Texas Motor Freight Sys. Inc. v. Rodriguez*, 431 U.S. 395, 403 (1977)); *see also Alston v. Virginia High School League, Inc.*, 184 F.R.D. 574, 581 (W.D. Va. 1999). Plaintiffs' simple announcement that "[n]o conflict of interest exists as all members of the Class would desire to recover damages for any economic injury sustained because of the purchase of Digitek®," (Doc. 283-1, 45), does not suffice.

For example, Plaintiffs want to apply New Jersey law to the entire action. As explained by the New Jersey Supreme Court, however, "the PLA [*i.e.*, Product Liability Act] is the sole source of remedy for plaintiffs' defective product claim; therefore, the Consumer Fraud Act

(CFA), N.J.S.A. 56:8-1 to -106, does not provide an alternative remedy." *Sinclair v. Merck & Co., Inc.*, 948 A.2d 587, 598 (N.J. 2008). In fact, the PLA governs all product-related actions in New Jersey, "*irrespective of the theory underlying the claim*, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1b(3) (emphasis added). Thus, all but Plaintiffs' express warranty claims are blocked by the PLA. Moreover, the PLA requires a physical injury. *Sinclair*, 948 A.2d at 595. "Economic-only," product-related class actions simply have no place in New Jersey as a result. *See Levinson v. Johnson & Johnson Con. Cos.,* No. 09-CV-3317, 2010 WL 421091, at *6-7 (D.N.J. Feb. 1, 2010) (dismissing "economic only" class action complaint attempting to assert NJCFA, implied warranty, and unjust enrichment claims relating to baby wash because such a claim does not exist under the PLA). Thus, Plaintiffs' adequacy is called into question by their request to impose this law nationwide.

Another adequacy hurdle for Plaintiffs is their decision to seek only economic damages. *See, e.g.*, *In re Teflon Prods. Liab. Litig.*, 254 F.R.D. 354, 368 (S.D. Iowa 2008) (holding representatives risked future waiver of class members' personal injury claims by disavowing them); *Feinstein v. Firestone Tire & Rubber Co.*, 535 F. Supp. 595, 606 (S.D.N.Y. 1982) (holding that representatives' willingness to risk waiver by splitting claims raises "a serious question of adequacy of representation"). Even the named Plaintiffs themselves seemed troubled by the possibility of preclusion. (*See, e.g.*, Wilburn Dep., Exh. G, at 98:17-22; 99:6-11.) And the conflict is nowhere more apparent than in the case of Plaintiff Whitaker, whose counsel maintains that Ms. Whitaker personally asserts a wrongful death claim despite the fact she only seeks economic damages on behalf of the proposed class. (Whitaker Dep., Exh. K, at 69:23-70:1; York Compl., Exh. F.) *See also Broussard*, 155 F.3d at 337-39 (holding that the conflict

between those who sought restitution and those who sought damages rendered named plaintiffs not typical).

In sum, Plaintiffs cannot satisfy Rule 23(a)(4)'s adequacy requirement, and this failure alone supports a denial of their class certification request.

II. Plaintiffs Also Fail to Show That the Rule 23(b)(3) Predominance and Superiority Requirements Are Met.

A. Common issues do not predominate because, as a proper choice-of-law analysis would have shown, all 50 states' laws must be applied.

Because Plaintiffs purport to represent a multi-state class, they were required to provide the Court with a full analysis of state-law variations and a plan for how any difficulties could be managed at trial. *Gariety*, 368 F.3d at 370. They did neither. "The plaintiffs have the burden of showing that common questions of law predominate, and they *cannot meet this burden when the various laws have not been identified and compared*." *Id.* (emphasis added); *see also Cole v. General Motors Corp.*, 484 F.3d 717, 724 (5th Cir. 2007) (one of many courts requiring "extensive analysis" of state-law variations); *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 340 (D.N.J. 1997) (same). Far from conducting an "extensive analysis," Plaintiffs claim they only need to conduct a "limited" choice-of-law analysis (Doc. 283-1, 28), after which they offer a misguided analysis that they maintain supports nationwide application of New Jersey law. In truth, all 50 states' laws must be applied to resolve the claims of the proposed class, which, in turn, destroys any chance of a nationwide class in this litigation.

1. A proper choice-of-law analysis points in all directions, not just toward New Jersey.

Because the parties here have not consented to a consolidated complaint, this Court applies the choice-of-law tests of the transferor courts. *See, e.g.*, PTO No. 33, MDL No. 1968, *In re Digitek® Prods. Liab. Litig.*, Doc. 177 (citing cases); *In re ConAgra Peanut Butter*, 251

F.R.D. at 693; *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 140 (E.D. La. 2002). Plaintiffs assert four claims – statutory consumer-fraud claims, and claims for implied warranty, express warranty, and unjust enrichment – and each must be considered under the choice-of-law standards in each of the four transferor jurisdictions (Kansas, Kentucky, New Jersey, and West Virginia)[108] This analysis shows that the proposed multistate class should not be certified.

(a) Kansas choice-of-law analysis.

Kansas resident Peter Konek filed his action in Kansas, seeking nationwide certification of a class under Kansas laws. Plaintiffs do not dispute that their statutory fraud claim under Kansas law is governed by the *lex loci delicti* choice-of-law test that Kansas courts apply to tort claims. Under this test, the "place of the wrong" controls, defined as the location where the last event necessary to impose liability occurred. *Ling v. Jan's Liquors*, 703 P.2d 731, 735 (Kan. 1985). For misrepresentation or omission claims, the last event "is where the loss is sustained, not where the fraud or misrepresentations were made." *Steele v. Ellis*, 961 F. Supp. 1458, 1463 (D. Kan. 1997); *accord, e.g.*, *Cummings v. LTC, Inc.*, Civ. A. No. 91-2002-GTV, 1993 WL 119668, at *5 (D. Kan. Mar. 5, 1993). Thus, contrary to Plaintiffs' assertion that a Kansas court would apply only Kansas law, it instead would apply the law of each state in which Plaintiffs incurred Digitek-related expenses.[109] This refusal to export Kansas law is consistent with the fact that the Kansas statute applies only to violations occurring in Kansas. K.S.A. § 50-638(a).

Warranty claims in Kansas are governed by a *lex loci contractus* test, which mandates application of Kansas law so long as the transaction bears "an appropriate relation" to Kansas.

[108] Despite the economic-only nature of Plaintiffs' claims, Plaintiffs discuss only the tort-based choice-of-law test of each transferor jurisdiction. In fact, each jurisdiction takes a unique view of whether the four claims asserted are subject to a tort or contract choice-of-law test.

[109] *E.g. Sunbird Air Servs., Inc. v. Beech Aircraft Corp.*, No. 89-2181-V, 1992 WL 193661, at *6 (D. Kan. July 15, 1992) (denying certification; law of all states where class members suffered harm would apply).

K.S.A. § 84-1-105(1).[110] Again, the end result is that a Kansas court would apply all 50 states' laws, as it could not apply its own law to class members with no ties to Kansas.

Plaintiffs' unjust enrichment claim similarly calls for consideration of all 50 states' laws under the Kansas analysis; although the precise choice-of-law test is unclear, the result is the same whichever test applies. *Compare Cummings*, 1993 WL 119668, *5 (applying *lex loci contractus*) *with Sunbird*, 1992 WL 193661, at *7 (applying Rest. (2d) Conflict of Laws § 221 factors: (1) where benefit was received, (2) where benefit was conferred, (3) domicile of the parties, and (4) location of the *res* at issue when benefit was conferred).

(b) Kentucky choice-of-law analysis.

Kentucky plaintiff Lorena Ard and Indiana plaintiff Judy Whitaker (on behalf of her mother, who was a Kentucky resident) filed the *York* complaint in Kentucky seeking to certify a statewide Kentucky class. Plaintiffs say that Kentucky's "*any* significant contacts" test applies, and somehow interpret this as "point[ing] unambiguously to the application of New Jersey law." (Doc. 283-1 at 28, 30 n.27.) They confuse Kentucky's "any significant contacts" test – which applies to tort claims (including the statutory fraud and unjust enrichment claims) under Kentucky law[111] – with the Restatement's "*most* significant contacts" test. The tests are very different. Kentucky's test is essentially a *lex fori* test that presumes Kentucky law applies:

> First, as a starting presumption, there is "no doubt Kentucky prefers the application of its own laws over those of another forum." Second, although this principle should generally dictate the outcome, there are occasions when a careful examination of the facts reveals that the case's actual connection to Kentucky is simply too remote to justify applying Kentucky law.

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[110] *Cf. Sunbird*, 1992 WL 193661, at *6 (noting that implied warranty claims alleging personal injury or property damages, not mere economic loss, are subject to *lex loci delicti* tort test).

[111] *Custom Prods., Inc. v. Fluor Daniel Canada, Inc.*, 262 F. Supp. 2d 767, 771 (W.D. Ky. 2003). *See also Tractor and Farm Supply, Inc. v. Ford New Holland, Inc.*, 898 F. Supp. 1198, 1206 (W.D. Ky. 1995) (applying this tort standard to an unjust enrichment claim).

Custom Prods., 262 F. Supp. 2d at 771 (internal citation omitted). Thus, a Kentucky court would apply Kentucky law at least to the claims of putative class members having Kentucky ties, and possibly to many others. It would not apply New Jersey law nationwide.[112]

As for Plaintiffs' warranty claims, a Kentucky court would apply "the law of the state with the greatest interest in the outcome of the litigation." *Bonnlander v. Leader Nat'l Ins. Co.*, 949 S.W.2d 618, 620 (Ky. Ct. App. 1996). Under this test, Kentucky courts consider factors such as the location of the purchase of the product, the residency of the person purchasing the product, the residency of the person initiating the action, the location where the injury occurred, and the residency of the parties involved. *See Breeding v. Massachusetts Indem. & Life Ins. Co.*, 633 S.W.2d 717, 719 (Ky. 1982). These factors again point to applying all 50 states' laws.

(c) New Jersey choice-of-law analysis.

Campbell, *Chambers*, and *Wilburn* were filed in New Jersey, but only Alan Chambers has any connection to that state. New Jersey law would apply to his claims, but all other named plaintiffs (and the vast majority of proposed class members) lack any contacts with New Jersey. Plaintiffs are wrong to suggest a New Jersey court would apply its law nationwide.

For both tort and contract claims, New Jersey courts apply the "most significant relationship" test. *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437 (D.N.J. 2009). The first step is to determine whether a conflict actually exists; if so, the second step is to apply the "most significant relationship" factors from the pertinent Restatement section. *P.V. v. Camp Jaycee*, 197 N.J. 132, 143-44 (N.J. 2008). There is little question that the laws of the various states conflict as to statutory fraud, breach of warranty, and unjust enrichment. *See Agostino*, 256

[112] Nor could a Kentucky court export its own consumer law nationwide. That law applies only if at least one of the parties, or the underlying transaction, has Kentucky ties. Ky. Rev. Stat. § 367.220(1).

F.R.D. at 461 (explaining unique features of NJCFA). Therefore, a New Jersey court would consider the "most significant contacts" factors applicable to each cause of action.

For Plaintiffs' statutory fraud claim, which sounds in fraud and misrepresentation under New Jersey law, three separate sets of factors (listed in the following chart) must be considered to determine the state with the "most significant contacts." *Clark v. Prudential Ins. Co.*, No. 08-6197, 2009 WL 2959801, at *7 (D.N.J. Sept. 15, 2009); *Camp Jaycee*, 197 N.J. at 147. Those that weigh in favor of applying all 50 states' laws are shown in **bold**, and those that weigh in favor of the law of Defendants' home states are underlined (others are neutral or inapplicable):

Step One: § 148(2) factors	Step Two: § 145(2) factors	Step Three: § 6 factors
(a) the place, or places, where the plaintiff acted in reliance upon the defendant's representations,	(a) the place where the injury occurred;	(a) the interests of interstate comity;
(b) the place where the plaintiff received the representations,	(b) the place where the conduct causing injury occurred;	(b) the interests of the parties;
(c) the place where the defendant made the representations,	**(c) the domicile, residence, nationality, place of incorporation, and place of business of the parties, and**	(c) the interests underlying the field of tort law;
(d) the domicile, residence, nationality, place of incorporation and place of business of the parties,	(d) the place where the relationship, if any, between the parties, is centered.	(d) the interests of judicial administration; and
(e) the place where a tangible thing which is the subject of the transaction between the parties was situated at the time, and		**(e) the competing interests of the states.**
(f) the place where the plaintiff is to render performance under a contract which he has been induced to enter by the false representations of the defendant.		

Each putative class member's home state will have the most significant contacts. The class member resides there, of course, while Defendants are headquartered in three separate states; putative class members bought and used Digitek® in all 50 states; and each home state has a strong interest in regulating these transactions. There is no support for Plaintiffs' argument that New Jersey law should apply to all claims simply because a defendant is headquartered there. To the contrary, "the simple expedient of selecting a defendant's home state law for the apparent

purpose of facilitating a nationwide class action strongly resembles the 'bootstrapping' criticized by the U.S. Supreme Court in *Shutts*." *Thompson v. Jiffy Lube Int'l., Inc.*, 250 F.R.D. 607, 627 (D. Kan. 2008).[113] New Jersey precedent is in accord. *See*, *e.g.*, *Agostino*, 256 F.R.D. at 463; *Clark*, 2009 WL 2959801, at *16; *In re Ford Ignition Switch Litig.*, 174 F.R.D. at 348; *see also Nafar v. Hollywood Tanning Sys., Inc.*, No. 08-3994, 339 Fed. Appx. 216, 2009 WL 2386666, at *6 (3d Cir. Aug. 5, 2009) (unpublished) (vacating order that certified nationwide NJCFA class and directing district court to follow choice-of-law principles set forth in *Agostino*).

Plaintiffs ignore this precedent and instead rely on a decision that is not only distinguishable, but is currently under reconsideration in light of *Nafar*. *See In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46 (D.N.J. 2009) (exporting NJCFA nationwide); *but see In re Mercedez-Benz Tele Aid Contract Litig*., Civil Docket Sheet, Case No. 2:07-cv-02720-DRD-MAS, at Dkt. #124, 131 (reflecting pending motions to decertify class in light of *Nafar*) (Exh. W). Reading Plaintiffs' brief, one might think New Jersey-based Actavis is the only defendant. (Doc. 283-1, 29 ("[A]ll the critical contacts were with New Jersey.").) But Plaintiffs are also pursuing claims against Defendants based in Illinois, Pennsylvania, West Virginia and Texas. Therefore, even on the defendant side of the choice-of-law equation, multiple states have an interest in the underlying transactions – unlike the *Mercedes* case, in which the court noted

[113] *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985), explains the constitutional importance of the forum state's connection to the plaintiff. Plaintiffs' reliance on *Shutts* and *Franchise Tax Board v. Hyatt*, 438 U.S. 488 (2003), ignores the importance of viewing the transaction from the plaintiff's perspective. Also, their *Franchise Tax* analogy fails because (1) that case was not a proposed nationwide class action, and (2) the forum applied its own law not only because the plaintiff was connected to that forum, but also because it was undisputed that some of the alleged misconduct occurred in the forum state. *Id*. at 495.

that New Jersey was the only state with an interest in regulating a resident corporation. *Mercedes*, 257 F.R.D. at 59.[114]

As for Plaintiffs' unjust enrichment claim, New Jersey courts consider the following "most significant contacts" factors:

- the place where a relationship between the parties was centered, provided that the receipt of enrichment was substantially related to the relationship,
- the place where the benefit or enrichment was received,
- the place where the act conferring the benefit or enrichment was done,
- the domicile, residence, nationality, place of incorporation and place of business of the parties, and
- the place where a physical thing, such as land or a chattel, which was substantially related to the enrichment, was situated at the time of the enrichment.

Rest. (2d) Conflict of Laws § 221(2) (Restitution). Applying these to the facts here once again leads to the conclusion that the law of each putative class member's home state should govern their claims. Indeed, every single one of these factors supports such an outcome.

Plaintiffs' warranty claims sound in contract under New Jersey law, and the "significant contacts" relevant in contract disputes lacking a written choice-of-law provision include:

- the place of contracting,
- the place of negotiation of the contract,
- the place of performance,
- the location of the subject matter of the contract, and
- the domicile, residence, nationality, place of incorporation and place of business of the parties.

[114] Plaintiffs cite only one other case for the proposition that the NJCFA can be exported nationwide. *Elias v. Ungar's Food Prods., Inc.*, 252 F.R.D. 233 (D.N.J. 2008). That case involved only New Jersey defendants, and, more notably, the court did not undertake any choice-of-law analysis.

Rest. (2d) Conflict of Laws § 188(2); *see also Glynwed, Inc. v. Plastimatic, Inc.*, 869 F. Supp. 265, 270 (D.N.J. 1994). Again, all of these factors point to applying the laws of 50 states here.

In the end, each of the applicable choice-of-law tests in New Jersey leads to the conclusion that in this case, New Jersey law cannot fairly be applied nationwide.

(d) West Virginia choice-of-law analysis.

The *Lange* case was originally filed in West Virginia by Kentucky resident William Lange. It is unclear whether, in West Virginia, Plaintiffs' statutory fraud claim is subject to the state's choice-of-law test for contract claims (the Restatement's "most significant contacts" test) or its test for tort claims (*lex loci delicti*). *Compare Pen Coal Corp. v. William H. McGee & Co., Inc.*, 903 F. Supp. 980, 983-84 (S.D. W. Va. 1995) (Goodwin, J.) *with State of West Virginia ex rel. Chemtall Inc. v. Madden*, 607 S.E.2d 772, 780 (W. Va. 2004). In every case analyzing choice-of-law in a statutory fraud context, the court has applied the contract test, but each of those cases involved an insurance contract. *E.g.*, *Pen Coal Corp.*, 903 F. Supp. at 983-84. As for Plaintiffs' warranty claims, a West Virginia court would apply the state's choice-of-law test for tort claims. *City of Bluefield v. Autotrol Corp.*, 723 F. Supp. 362, 364 n.3 (S.D. W. Va. 1989). But the appropriate test is again unsettled with respect to Plaintiffs' unjust enrichment claim.

Regardless, as the *lex loci delicti* and "most significant contacts" analyses above demonstrate, the end result would be the same: a West Virginia court would apply the laws of each state in which the class members bought Digitek®.

2. Because state laws conflict, common issues do not predominate.

Plaintiffs repeatedly claim, in conclusory fashion, that the substantive laws of the four transferor states do not vary, and they entirely fail to address the substantive laws of the remaining 46 states. At most, they recite some black-letter law from a few jurisdictions and

jump to the conclusion that one state's law can apply nationwide. But a "largely textual presentation of legal authority oversimplifie[s] the required analysis and gloss[es] over the glaring substantive legal conflicts among the applicable laws of each jurisdiction." *General Motors*, 484 F.3d at 725-26; *see also Walsh v. Ford Motor Co.*, 807 F.2d 1000, 1016 (D.C. Cir. 1986) (noting that even "[t]he Uniform Commercial Code is not uniform."). It is Plaintiffs' burden, not Defendants', to survey the law, but even a brief review shows that statutory fraud, express and implied warranty, and unjust enrichment claims are unsuitable for nationwide certification due to the predominance of individualized legal issues.

(a) Nationwide certification of statutory fraud claims is improper.

"State consumer protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules." *In re Bridgestone/Firestone*, 288 F.3d at 1018. For instance, many consumer protection acts prohibit class actions. Ala. Code § 8-19-10(f) (2010); Ga. Code Ann. § 10-1-399(a) (Michie 2010); Miss. Code Ann. § 75-24-15(4) (2010); Mont. Code Ann. § 30-14-133(1) (2010); S.C. Code Ann. § 39-5-140(a) (Law Co-op. 2010). Some states allow only the government or a limited subset of citizens to pursue violations of their consumer protection statute. *E.g.*, Iowa Code § 714.16 (West 2010) (prohibiting private actions altogether); Ark. Code Ann. § 4-88-204 (Michie 2010) (limiting private actions to elderly and disabled persons). Yet Plaintiffs here seek to assert consumer claims on behalf of everyone nationwide – including people who would not be able to bring such claims in their own home state. This approach runs afoul of the Rules Enabling Act, which prohibits procedural rules like Rule 23 from abridging, enlarging, or modifying substantive rights. 28 U.S.C. § 2072(b).

Even in states that permit private consumer class actions, the laws differ substantively. In some states, plaintiffs must prove they relied on the alleged deceptive act.[115] Other states do not expressly require reliance, but still require some form of causation in that they require plaintiffs to prove they sustained some ascertainable loss *as a result of* the alleged deception.[116] Some statutes require the plaintiff prove an "intent to deceive," while others do not.[117] Some require the plaintiff to show awareness of the alleged falsity, while others do not.[118, 119] Similarly, some states require pre-suit notice to the defendant or attorney general.[120] Others do not.

Given the extensive variations just outlined, none of the original forum states' laws could be said to be representative of the laws of all 50 states. *In re Prempro,* 230 F.R.D. 555, 564 (E.D. Ark. 2005) ("consumer fraud . . . laws of the states differ with regard to the defendant's state of mind, type of prohibited conduct, proof of injury-in-fact, available remedies, and reliance, just to name a few differences."); *Jiffy Lube*, 250 F.R.D. at 625 (also noting that consumer protection laws vary; denying proposed nationwide consumer class because plaintiff oversimplified actual elements of statutes involved and the effect on individual claims).

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[115] *See, e.g.*, Ind. Code § 24-5-0.5-4 (2010); Cal. Bus. & Prof. Code §§ 17203-04 (2010) .

[116] *E.g., Avery v. State Farm Mut. Auto. Ins. Co.*, 835 N.E.2d 801 (Ill. 2005) (holding proximate cause required); *In re St. Jude Med., Inc.*, 522 F.3d 836, 839-40 (8th Cir. 2007) (holding Minnesota statute does not require reliance but does require individualized causation; denying class certification).

[117] *Compare Bond Leather Co., Inc. v. Q.T. Shoe Mfg. Co., Inc.*, 764 F.2d 928, 937 n.6 (1st Cir. 1985) (holding proof of intent to deceive not required under Massachusetts statute); *with* 6 Del. Code Ann. § 2513(a) (2010) (requiring proof of intent to deceive under Delaware Consumer Fraud Act).

[118] *Compare Forbes v. Par Ten Group, Inc.*, 394 S.E.2d 643, 651 (N.C. Ct. App. 1990) (knowledge of falsity not required) *with Stevenson v. Louis Dreyfus Corp.*, 811 P.2d 1308, 1311 (N.M. 1991) (knowledge of falsity is required).

[119] Among Plaintiffs' "common questions" are "(i) Whether Defendants failed to give adequate and timely warning of the problems with Digitek [and] (m) Whether Defendants concealed information about the problems with Digitek from the FDA, Plaintiffs and the members of the Class." (Doc. 283-1, 40-41.)

[120] *E.g.*, Ala. Code § 8-19-10(e) (2010) (must provide 15 days written notice); Cal. Civ. Code § 1782 (2010) (30 days); Conn. Gen. Stat. § 42-110g(c) (2010) (notice to attorney general required); K.S.A. 50-634(g) (notice to attorney general is required, but failure to give notice is not a defense).

(b) Nationwide certification of warranty claims is improper.

Plaintiffs assert claims for breach of an implied warranty of merchantability and breach of express warranty. But the warranty laws of the 50 states are not uniform. For one thing, in many states Plaintiffs' proposed implied warranty claims could not proceed because Plaintiffs, who bought Digitek® from a pharmacy, lack privity with any Defendant.[121] Other states do not require privity. *E.g., SCM Corp. v. Deltak Corp*., 702 F. Supp. 1428, 1433-34 (D. Minn. 1988). In some states, it depends on the kind of injury alleged. In Illinois, for example, privity is not required if the alleged breach caused a physical injury, but it is required if only economic injuries are at issue. *See Jensen v. Bayer AG*, 862 N.E.2d 1091, 1099-1100 (Ill. App. Ct. 2007) (dismissing class action complaint based on warranty because disavowal of personal injury claims made privity an issue, but plaintiff bought recalled drug from a pharmacy). *Id.*

Some states also require that the plaintiff provide the defendant with notice of the alleged breach of warranty before filing suit, although the nature of the required notice varies. *See Cotner v. Int'l Harvester Co.*, 545 S.W.2d 627, 630 (Ark. 1977) (notice required); *Royal Typewriter Co. v. Xerographic Supplies Corp.*, 719 F.2d 1092, 1102 (11th Cir. 1983) (under state law, notice may be informal); *Eaton Corp. v. Magnavox Co.*, 581 F. Supp. 1514, 1531-32 (E.D. Mich. 1984) (under Michigan law, notice must be express).

Other variations relate to the proof the plaintiff must present to recover. *See*, *e.g.*, *Scaringe v. Holstein*, 477 N.Y.S.2d 903, 904 (N.Y. App. Div. 1984) (proof of actual reliance on required); *Baughn v. Honda Motor Co.*, 727 P.2d 655, 669 (Wash. 1986) (requiring at least awareness of the express statement under Washington law). Finally, some states preclude

[121] *See, e.g.*, *TWM v. Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995); *Horn v. A.O. Smith Corp.*, 884 F. Supp. 1226, 1244 (N.D. Ind. 1994); *Omka v. Hoecht Celanese Corp.*, 528 N.W.2d 103, 108 (Iowa 1995); *Munn v. Pfizer Hosp. Prods. Group, Inc.*, 750 F. Supp. 244, 248 (W.D. Ky. 1990).

simultaneous pursuit of both implied and express warranties. *E.g.*, *Gilmore v. General Motors Corp.*, 300 N.E.2d 259, 263 (Ohio Com. Pl. 1973) (stating, under Ohio law, plaintiff cannot pursue both express and implied warranty claim on same facts). Especially problematic for Plaintiffs here is that "courts in many jurisdictions have held that a plaintiff *must* demonstrate an actual manifestation of the alleged defect to sustain a cause of action for breach of the implied warranty of merchantability." *Rule v. Fort Dodge Animal Hosp., Inc.*, 604 F. Supp. 2d 288, 294 (D. Mass. 2009) (emphasis in original) (collecting cases). The *Rule* court granted the defendant's motion to dismiss an implied warranty claim because the plaintiff had used up all of the recalled product (a dog medicine), and did not allege it had failed to work. *Id.* at 296.

In light of the variations in warranty law discussed above, courts routinely reject nationwide certification of such claims for class treatment. *See*, *e.g.*, *General Motors*, 484 F.3d at 726 ("Specifically, the [express and implied warranty] laws of the jurisdictions vary with regards to (1) whether plaintiffs must demonstrate reliance, (2) whether plaintiffs must provide notice of breach, (3) whether there must be privity of contract, (4) whether plaintiffs may recover for unmanifested [product] defects, [and] (5) whether merchantability may be presumed . . . ."); *In re Ford Motor Co. Bronco II Prod. Liab. Litig.*, 177 F.R.D. 360, 369 (E.D. La. 1997) (rejecting nationwide certification of breach of warranty claims because one state's law could not be applied to all claims); *Sunbird*, 1992 WL 193661, at *6-7 (same); *Firestone Tire*, 535 F. Supp. at 605 ("[E]ven within the U.C.C. implied warranty umbrella, state law may differ in such significant areas as vertical privity and the availability of punitive damages.").

(c) Nationwide certification of unjust-enrichment claims is improper.

As explained by one Kansas court, unjust-enrichment claims are generally not suitable for nationwide certification, again because the law varies widely:

> [T]here are differences nationwide in the very definition of unjust enrichment and its availability as a remedy. Some states preclude such claims when an adequate legal remedy is available, and many states say the existence of an enforceable contract will preclude an unjust enrichment claim. Because of such variations, federal courts have generally refused to certify a nationwide class based upon a theory of unjust enrichment.

Jiffy Lube, 250 F.R.D. at 626; *see also, e.g.*, *Gilman v. John Hancock Variable Life Ins.*, No. 02-0051AB, 2003 WL 23191098, at *13 (Fla. Cir. Ct. Oct. 20, 2003) (also noting variations in unjust enrichment laws as to level of misconduct required and affirmative defenses available). *Accord, e.g., In re Bridgestone/Firestone*, 288 F.3d at 1020; *In re Rezulin Prods.*, 210 F.R.D. at 68-69; *In re PPA*, 214 F.R.D. at 616; *Clay v. American Tobacco Co*., 188 F.R.D. 483, 500 (S.D. Ill. 1999); *Commander Props., Inc. v. Beech Aircraft Corp*., 164 F.R.D. 529, 541 (D. Kan. 1995); *Sunbird*, 1992 WL 193661, at *6-7 (same).

B. State-specific certification is also unwarranted.

Plaintiffs focus almost exclusively on a request for nationwide certification, but in cursory fashion they request, in the alternative, certification of state-specific classes in Kansas, Kentucky, New Jersey, and West Virginia, and request permission to seek additional state-specific classes at a later date. Their "analysis" in support of the four statewide class actions is contained in a single paragraph (Doc. 283-1, 54-55), in which they cite no cases, fail to discuss the suitability of their claims for class treatment under each state's laws, and fail to mention any of the Plaintiffs. This back-of-the-hand treatment is unacceptable and, on its own, warrants a denial of their state-specific requests.[122] This is particularly true given that two of the underlying actions – *Chambers* and *York* – requested statewide, not nationwide, certification from the outset. (*Chambers* Compl. ¶ 5, Case No. 2:08-cv-1175, Doc. 31; *York* Compl. ¶ 1, Exh. F.) Plaintiffs'

[122] To the extent Plaintiffs may be planning to expand on this in their reply brief, any new matter raised in a reply brief should be rejected. If Plaintiffs are permitted to file separate state-specific requests at any time, Defendants request leave to respond separately as well.

plea for additional time to drum up state-specific classes in the remaining 46 states should be rejected. As with choice-of-law, however, while Plaintiffs have the burden, Defendants highlight the following highly individualized factual and legal issues that preclude certification of even statewide class actions.

1. Highly individualized factual issues.

To resolve each putative class member's claim, a trier of fact would be required to consider the following highly-individualized factual evidence, much of which involves issues that Plaintiffs wrongly suggest are "common":

- **Product identification.** Some representatives are unable to prove they ever took Digitek®, as opposed to some other form of digoxin. (*See, e.g.*, Whitaker Dep. at 51:20-22; 94:19-25; 127:13-16.) Product identification generally cannot be proven on a common basis in any event. *Martin v. Home Depot U.S.A., Inc.*, 225 F.R.D. 198, 203 (W.D. Tex. 2004); *see also Rhodes*, 253 F.R.D. at 374-75 (finding evidence insufficient to show exposure level was amenable to class-wide proof).

- **Benefit of the bargain:** Again, Konek fully acknowledges that the Digitek® he ingested was effective. (Konek Dep., 55:11-56:11; *see also* Chambers Dep. at 118:22-119:18, conceding effectiveness.) In contrast, Whitaker believes in retrospect that the Digitek® she claims her mother ingested caused her to suffer physical injuries. (Whitaker PFS at 5, Exh. L.) Dr. Kernan's expert report establishes that determining the benefit an individual may have received from Digitek® is an individualized inquiry. (Exh. B, at ¶¶ 6.4; 6.4.1.)

- **Existence and extent of economic loss:** Milligan returned Digitek® tablets and received replacement digoxin at no charge. (Milligan Dep. at 164:12-15.) Chambers seeks to recover expenses he acknowledged he would have incurred regardless of the recall (*e.g.*, co-pays for standing doctor's appointments). (Chambers Dep. at 31:2-18.) Moreover, Plaintiffs seek much more than refunds, they all seek a wide assortment of highly unique damages, such as the cost of new glasses, toll charges, insurance premiums, and even the cost of two enemas.

- **Participation in refund program:** Whether a particular individual has already been compensated for leftover Digitek®, either as part of the Stericycle refund process or otherwise, is another individual issue. (*See* Bird Aff. at 10-12, 15 (discussing public participation in the refund program); *see also* Milligan Dep. at 164:12-15 (exchanged remaining Digitek® for another brand at no cost).)

- **Plaintiffs' own conduct:** Some class members continued to use Digitek® after learning of the recall, and some did not. Mr. Pasken, for example, testified he merely broke his tablets in half and took the half-tablets after learning of the recall. (Pasken Dep. at 46:14-20.)

- **Third-party involvement.** To the extent the conduct of third parties such as pharmacists or doctors may be relevant, such as with regard to the recall program and/or what Plaintiffs may have been told if they contacted their health-care providers, that also is not subject to common proof. *See Lienhart v. Dryvit Sys., Inc.*, 255 F.3d 138, 148 (4th Cir. 2001) (addressing possible third-party conduct in economic-loss mass-tort claim).

These types of individualized factual inquiries tie directly to the proof each putative class member must present to establish the legal elements of the claim asserted.

2. Highly individualized legal issues.

Limiting a class definition to a single state would not avoid the need to analyze choice-of-law issues. "[T]he mere fact that suit is brought in a state does not make it appropriate to apply the substantive law of that state." K.S.A. 84-1-105, off. cmt. 2 (2002); *accord, e.g.*, *Systems Design & Mgmt. Inf., Inc. v. Kansas City Post Office Employees Credit Union*, 788 P.2d 878, 881 (Kan. Ct. App. 1990) (arbitrary or unfair application of Kansas law not permitted). Consider, for example, a named plaintiff with no ties to the jurisdiction, such as Campbell (a Pennsylvania resident who filed in New Jersey), Chambers (a New Jersey resident who filed in West Virginia), Lange (a Kentucky resident who filed in West Virginia), Wilburn (an Illinois resident who filed in New Jersey), and Pasken (a Florida resident who filed in New Jersey). The law applicable to the individual claims is not necessarily that of the forum in which they filed suit. Similarly, not everyone living in a state at the time of class notice would necessarily have lived in that state at the time of the relevant events. Individual analyses of the type sketched out below under each of the four states' laws would be required to ensure proper application of law.

(a) Individualized legal issues in Kansas.

Kansas Consumer Protection Act ("KCPA") claims cannot be resolved on a classwide basis. *See, e.g.*, *Benedict v. Altria Group, Inc.*, 241 F.R.D. 668 (D. Kan. 2007). The proposed class in *Benedict* was limited to those who bought defendant's light and low-tar cigarettes in Kansas. *Id*. at 671, 676. The court held that each class member must individually prove he suffered a loss *as a result of* relying on the defendants' allegedly deceptive practice. *Id.* at 676-78. In so holding, it rejected the argument Plaintiffs assert here that the KCPA does not require a showing of individualized reliance:

> It is possible that defendants' practices constitute a per se violation of the KCPA . . . regardless of whether any consumer was actually misled by defendants' statements regarding light cigarettes. But that does not mean [plaintiff] may automatically recover. [T]his court rules she must establish a causal connection between defendants' statements and her loss, *i.e.*, she must show she relied on defendants' statements in purchasing light cigarettes.

Id. at 678. The court also rejected the plaintiffs' argument that only the named plaintiff must show this causal connection, "even if the result [of this holding] is [that] *very* few class certifications [are certified] in misrepresentation cases." *Id*. at 679-80 (emphasis in original). The *Benedict* court also held that individual issues relating to damages and affirmative defenses (*e.g.*, comparative fault) precluded certification of the plaintiffs' KCPA claim. *Id*. at 680. This echoed an earlier decision also concluding that a KCPA claim was not amenable to classwide resolution:

> While a common question of law is shared by all class members, *i.e.*, whether defendants' alleged conduct violates the KCPA and other Kansas law, the determination of whether such deceptive acts actually occurred involves factual issues unique to each class member. . . . Inasmuch as these issues would require separate findings of fact for each class member, the court finds that certification of this class would not "achieve economies of time, effort, and expense . . . . without sacrificing procedural fairness [or] bring about undesirable results.

Skeet v. Sears, Roebuck & Co., 137 F.R.D. 347, 351 (D. Kan. 1991) (quoting Rule 23(b)(3)). Whether the purchase occurred in Kansas is another individualized issue. *E.g.*, K.S.A. § 50-624(c); *Kline v. Berry*, 137 P.3d 500 (Kan. App. 2006). Under this Kansas precedent, Plaintiffs' request for statewide KCPA certification fails.

Plaintiffs' express and implied warranty claims fare no better. *Loose v. Mitsubishi Motor Manf.*, Case No. 01 CV 7392, *slip op*. (Kan. Dist. Ct. July 9, 2003) (copy attached as Exh. X). In *Loose,* privity was an obstacle to class-wide resolution of both the express and implied warranty claims, and the express warranty claim was particularly problematic because each class member would need to present individualized basis-of-the-bargain evidence. *Id*. at 15-17*; accord Land v. Roper*, 531 F.2d 445 (10th Cir. 1976) (applying Kansas law; finding reliance on alleged warranty required). The same is true under the facts in this case.

As for Plaintiffs' Kansas unjust-enrichment claim, the elements include: (1) a benefit conferred on the defendant by the plaintiff; (2) an appreciation or knowledge of the benefit by the defendant; and (3) acceptance and retention of the benefit without payment of its value. *Holtorf v. Singh*, 204 P.3d 1191, 2009 WL 981814, at *4 (Kan. App. 2009). As noted, whether a consumer received the full benefit of Digitek, especially given the recall, refund and replacement program that was implemented, is a question that has varied answers even among the named representatives. Similarly, to the extent putative class members seek damages for Digitek consumed without incident (as suggested by the class definition), there cannot be an unjust enrichment. *See In re Rezulin*, 210 F.R.D. at 69.

(b) Individualized legal issues in Kentucky.

Similar to the Kansas statute, the Kentucky Consumer Fraud Act also requires a showing that a plaintiff suffered *an ascertainable loss as a result of* the allegedly deceptive act or practice. Ky. Rev. Stat. § 367.220(1) (2009). Thus, once again, each putative class member

would be required to not only allege and prove a deceptive act on the Defendants' part, but also to causally connect that deception to the purchase and use of Digitek®. Each putative class member must also prove a sustained injury, which cannot be done if the tablets were consumed without incident or if the putative class member has already been compensated through the refund program or otherwise.

Kentucky warranty law requires privity. *Compex Int'l Co., Ltd. v. Taylor*, 209 S.W.3d 462, 464 (Ky. 2006) (dismissing implied warranty claim against manufacturer due to lack of privity); *Anderson v. Merck & Co.*, 417 F. Supp. 2d 842, 848 (E.D. Ky. 2006) ("[T]he language of [KCFA] plainly contemplates an action by a purchaser against [his] immediate seller."). Privity requires individual proof (lacking here since Actavis did not sell directly to end users).

The elements of a Kentucky unjust-enrichment claim are similar, though not identical, to the elements under Kansas law. *See, e.g.*, *Realty Unlimited, Inc. v. Ball Homes, LLC,* No. 2007-CA-001658-MR, 2009 WL 50179, at *5 (Ky. Ct. App. Jan 9, 2009). Once again, individual proof that a particular individual has been compensated through the refund program or consumed Digitek without physical incident must be considered. *See also generally Eversole v. EMC Mortg. Corp.*, No. 05-124-KSF, 2007 WL 1558512, at *14 (E.D. Ky. May 29, 2007) (denying class certification of a Kentucky unjust enrichment claim).

(c) Individualized legal issues in New Jersey.

For the sake of brevity, the discussion in the Adequacy section above (*i.e.*, Part I(C)) regarding the intersection between the New Jersey Products Liability Act ("PLA") and Plaintiffs' NJCFA, implied warranty, and unjust enrichment claims will not be restated in full here. Suffice it to say that these three claims should never reach a jury because they are subsumed by the PLA yet they do satisfy the PLA's physical harm requirement. Even assuming, *arguendo*, Plaintiffs

had viable NJCFA, implied warranty, and unjust enrichment claims, however, these claims would be riddled by the need for individualized proof, which would preclude class treatment.

"To state a claim under the NJCFA, a private plaintiff must show (1) a violation of the Act; (2) that suffered an ascertainable loss as a result of the unlawful conduct; and (3) a causal relationship between the unlawful practice and the loss sustained by plaintiff." *Szczubelek v. Cendant Mortgage Corp.*, 215 F.R.D. 107, 121-22 (D.N.J. 2003) (denying proposed class of New Jersey homeowners asserting NJCFA claim because, *inter alia*, "under the NJCFA, loss is not assumed. Rather, it is an element that must be proven by each plaintiff.").

Plaintiffs ignore a similar New Jersey case in which the court found each plaintiff was required to individually prove a causal nexus between the alleged misrepresentations and his or her own unique loss. *Kleinman v. Merck & Co., Inc.*, 2009 WL 2481925 (pinpoint cites unavailable). The *Kleinman* plaintiffs argued that they satisfied the NJCFA's causal relationship requirement simply by alleging "defendant's misrepresentations and omissions allowed Vioxx to remain on the market despite its inherent health dangers." The judge – after assuring the plaintiffs he had taken into account the "strong policy of the CFA" – disagreed, finding individual proof of causation was necessary.

As another court held under the NJCFA, whether any individual class member "got his or her money's worth" is an inherently individual question:

> Plaintiffs' contention that everyone who took Rezulin sustained an ascertainable loss presumes that Rezulin was worthless. But that is not a defensible position. Even plaintiffs' experts acknowledge that Rezulin was enormously beneficial to many patients. Those patients presumably got their money's worth and suffered no economic injury. And the question whether an individual class member got his or her money's worth is inherently individual. Indeed, it involves very much the same questions as would a claim for money damages for personal injury.

In re Rezulin, 210 F.R.D. at 68-69.[123]

As for the possibility of a statewide warranty class action, New Jersey warranty law does not extend to cover allegedly defect products that, as to a particular individual, were not defective. *Yost v. General Motors Corp.*, 651 F. Supp. 656, 657-58 (D.N.J. 1986) (dismissing with prejudice a class action complaint focused on an alleged engine defect that had yet to manifest in the plaintiff's own car). Thus, each putative class member would be required to prove that Digitek® caused him *personally* a financial injury. This cannot be done without highly individualized evidence, as illustrated in Defendants' accompanying summary judgment motion regarding the sole New Jersey plaintiff, Alan Chambers.

Finally, a New Jersey unjust enrichment class would be plagued by the same problem discussed before: there is no unjust enrichment unless the defendant retains the benefit. *VRG Corp. v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994) ("To establish unjust enrichment, a plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust."). Given the extensive refund program, which many putative class members participated in, the question of Defendants' retention of any benefit is an individual, predominating question. Moreover, to the extent a putative class member took all of her Digitek® without incident, no improper benefit ever flowed Defendants' way.

(d) None of the named representatives can recover under West Virginia law.

Not only have Plaintiffs not bothered to analyze their request for a West Virginia-specific class action, they do not even offer a representative arguably entitled to recover under West Virginia law. The underlying West Virginia case (*Lange*) was filed by a Kentucky resident,

[123] The defendants in *Kleinman* and *In re Rezulin* do not appear to have specifically raised the question of whether an economic-only CFA action could proceed in light of the PLA.

whose own claims are governed by Kentucky law as discussed above. Given the lack of a proper class representative, Plaintiffs' request for certification of a class of "[a]ll persons residing in the State of West Virginia who purchased Digitek . . . ." should be denied outright.

In short, regardless of the jurisdiction or the cause of action, Plaintiffs have failed to carry their burden of proving that common factual and legal issues predominate in this litigation. In fact, a host of individual issues would predominate and would overwhelm any common issues that might exist.[124] For that reason as well, Plaintiffs' passing attempt at statewide certifications should be denied.

C. Plaintiffs have not shown that a class action would be a superior method of resolution.

Superiority of a class action to all other methods of resolution is a necessary condition to certification. *Gregory v. Finova Capital Corp.*, 442 F.3d 188, 190 n.3 (4th Cir. 2006). Plaintiffs correctly cite Rule 23(b)(3), but again simply state conclusions rather than conduct an analysis of how the rule's four considerations might apply in this case. (*See* Doc. 283-1 at 48-52.) There is no dispute, for example, that *if* certification is proper it may "reduce the overall costs of complex litigation" or provide an incentive that might not otherwise exist to pursue small claims. (*Id*. at 49.) There *is* a dispute as to whether those or the other relevant factors show that certification is proper in *this* case, and Plaintiffs offer virtually nothing to support their position that it is.

[124] The above does not exhaust the potentially individualized issues. For example, some plaintiffs may be subject to the economic-loss doctrine. *See In re Bronco II Litig.*, 177 F.R.D. at 369 (noting that states differ as to whether economic loss doctrine bars fraud claims, and that "[s]uch distinctions have been found to preclude certification of multiple jurisdiction classes."); *In re Ford Ignition Switch Litig.*, 174 F.R.D. at 350-51 (also noting state-law differences with regard to doctrine) Similarly, many states have laws specific to pharmaceutical products, governing matters such as the strict-liability standard, the learned-intermediary doctrine, and/or advertising disclosures. *In re Rezulin*, 210 F.R.D. at 70. Finally, to the extent Plaintiffs seek punitive damages, the variability of state law on that issue adds another layer of complexity. *See In re Baycol*, 218 F.R.D. at 215-16 (citing a variety of differing state laws on punitives).

1. Interest of class members in separate actions.

Plaintiffs rely entirely on the relatively small size of their claims when discussing this factor. (Doc. 283-1 at 50.) It is true that in some cases this weighs in favor of certification, but in others it does not. *See Gartin v. S&M NuTec LLC*, 245 F.R.D. 429, 442 (C.D. Cal. 2007) (noting this factor can "cut both ways" because cost of procedural requirements may outweigh efficiency gained). Plaintiffs do not show that it does here.[125] They make no attempt to show how the named representatives' claims support the application of this factor.

Some named representatives certainly have very small claims – Alan Chambers appears to seek just $15 in co-payments. (Chambers Dep. at 33:15-23; 117:3-14.) But Judy Whitaker is pursuing a wrongful-death action. (Whitaker Dep. at 69:23-70:1.) Lorena Ard seeks thousands in lost wages as well as damages for alleged emotional distress, meaning her claim, too, could be worth enough to be economically viable. (Ard. Dep. at 70:5-72:12; 98:12-15, 110:1-25.) Additionally, under at least some state consumer laws, a prevailing party may be able to recover attorneys' fees, a remedy specifically intended to make viable small claims that might otherwise be "negative-value suits." *See Castano v. American Tobacco Co.*, 84 F.3d 734, 748 (5th Cir. 1996) (rejecting certification partly for this reason). As the Court is aware, other plaintiffs are pursuing personal-injury claims as well as claims for economic losses, again demonstrating that others have their own interests in pursuing viable separate claims in the absence of certification.

[125] Plaintiffs suggest "it is likely" that many putative class members have either "not sought out counsel," or were turned away, because of the relatively low value of their cases. (Doc. 283-1, 59.) That is speculation. Especially given the many dismissals to date, it is equally likely that putative class members have not sought out counsel because they do not feel wronged or realize their claims are weak, not because the value is too low without certification. Plaintiffs have certainly not shown otherwise.

2. Extent and nature of existing litigation already commenced.

Plaintiffs offer only two sentences as to this factor. (Doc. 283-1 at 50.) One establishes only that they have read the notes to Rule 23; the other states that "many of the 'known' class members have already filed a suit against Defendants," but this fact cuts *against* certification:

> [T]he existence of litigation indicates that some of the interested parties have decided that individual actions are an acceptable way to proceed, and may even consider them preferable to a class action. Rather than allowing the class action to go forward, the court may encourage the [putative] class members . . . to intervene in the other proceedings.

7AA Wright, Miller and Kane § 1780 at p. 183; *see Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206, 222 (E.D. Pa. 2000) (fact that at least one putative class member previously sued and settled weighed against certification). Here, a number of plaintiffs and putative class members have resolved their cases by dismissing them outright. If few remain with any real interest in proceeding, the burden of a class action may not be justified when those few could intervene in other cases. Moreover, certification is not a superior method of resolution because it would impinge on Defendants' due process right to individually cross-examine each Plaintiff.

3. Desirability of concentrating the litigation in one forum.

This factor embodies two considerations: whether allowing the action would prevent duplication of effort and inconsistent results, and whether the particular forum is an appropriate place to adjudicate the controversy. 7AA Wright, Miller and Kane § 1780 at pp. 184-85. Neither weighs in favor of certification here.

First, given that Plaintiffs in this case have limited their claims to economic loss, there is an inherent duplication of effort and risk of inconsistency simply because other personal-injury suits are pending in which many of the same issues will be decided. Second, Plaintiffs do not

explain why West Virginia is a particularly appropriate forum for resolving this controversy, which may be because none of the named representatives are West Virginia residents. The underlying West Virginia case (*Lange*) was filed by a Kentucky resident whose claims, as discussed above, are governed by Kentucky law.

4. Manageability of the action.

Plaintiffs provide no meaningful guidance as to how the Court might manage the proposed class action, a matter they address in but a single paragraph. (Doc. 283-1, 52-53.) Their argument depends again on their assumption that New Jersey law can be applied to the entire matter. Because that is wrong, and because they provide no realistic plan for proceeding otherwise, certification should be denied.

When individual determinations must be made in a multistate action, certification may pose "massive manageability problems" for a court. *Schwartz v. The Upper Deck Co.*, 183 F.R.D. 672, 679 (S.D. Cal. 1999). Given that fact, courts have routinely held that in such cases it is part of a plaintiff's burden not only to fully analyze and compare the state laws involved, but also to provide a specific plan as to how such a complex and unwieldy trial could be managed. *See, e.g.*, *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1189 (9th Cir. 2001) (plaintiff must provide a "suitable and realistic plan for trial" taking different laws into account); *Gartin*, 245 F.R.D. at 442 (same); *In re Baycol*, 218 F.R.D. at 208 (plaintiff must demonstrate manageability with clearly defined classes based on state-law variations); 7AA Wright, Miller and Kane § 1780.1 at pp. 209-11 ("Only if that burden is met will Rule 23(b)(3) be deemed satisfied.") Proposed consumer-protection classes in particular frequently run afoul of this

limitation. 7AA Wright and Miller § 1780.1 at 218-21; *see, e.g.*, *Lyon*, 194 F.R.D. at 223 (holding management problems would arise from need to determine and apply applicable law). Plaintiffs have made no attempt at all to provide such a plan.

Plaintiffs suggest in passing that the Court would have little trouble creating and using a "unified jury instruction . . . , for instance, in determining Defendants' liability to class members." (Doc. 283-1 at 52.) They make that statement with regard to their alternative position that three states' laws might apply, but even if that were appropriate, Plaintiffs do not suggest what such a "unified liability instruction" might look like. Creating and using jury instructions or verdict forms based on many states' laws would be a mammoth task for everyone involved, not least the members of the jury. Numerous cases have held that the risk of error and jury confusion inherent in this weighs heavily against certification. *See, e.g.*, *In re Baycol*, 218 F.R.D. at 210; *In re Paxil Litig.*, 212 F.R.D. 539, 551 (C.D. Cal. 2003).

Finally, though the above problems should preclude certification, a class action may also be inferior to other methods even if relevant state laws are relatively uniform. In the *PPA* case, which was quite similar to this one, a court held that purported nationwide class claims limited to alleged economic losses resulting from a drug recall failed the superiority test, even assuming for the sake of argument that state laws were uniform. *In re PPA*, 214 F.R.D. at 614-21. There, too, the plaintiffs had failed to provide any sort of trial plan, and the court denied certification. *Id*. at 615. The plaintiffs then filed a renewed motion attempting to address the court's concerns about state-law variations, and submitted a trial plan. The court again denied certification.

First, the court noted that identifying class members would pose problems for reasons that also apply in this case. There, as here, some representatives had no proof that they actually bought and possessed the product, or how much they still had at the time of the recall. *Id.* at 617-19. Even setting aside the risk of fraud, the court found that class-member identification would "entail a host of mini-trials" that would defy a court's ability to manage the litigation. *Id.* at 620. Second, the court held that the desirability of making the pursuit of relatively small claims economically feasible (an argument Plaintiffs emphasize here) "does not eclipse the problem of unmanageability." *Id.* at 620-21. Third, the court held, other personal-injury lawsuits were pending that could serve at least some of the purposes of the proposed class action, such as punishment or deterrence (Konek's stated primary interest). *Id.* at 621. Finally, as here, the defendant in *PPA* had provided a refund program that offered much if not all of the redress plaintiffs were seeking. *Id.* at 621-23. That contributed to the court's conclusion that a class action was not superior, or even necessary, under the circumstances. For that reason, too, Plaintiffs have not shown that a class action would be a superior method of proceeding.

CONCLUSION

Plaintiffs have gone to great lengths to abandon or modify claims to make the putative class appear more cohesive, but now that the time has arrived to analyze whether or not certification is appropriate, they have made virtually no effort at all to meet their burden. They have asserted a nationwide class, but failed to analyze the complex choice-of-law issues that such litigation poses. They recite the elements of their claims but do not show what issues are truly common or that such predominate. In fact, as other courts have held in cases that also involved purported nationwide economic-loss-only classes asserting claims arising from product

recalls, such cases present highly individualized legal and factual issues that preclude certification. Plaintiffs' motion should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2010, a copy of the foregoing **Defendants' Brief Opposing Class Certification** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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